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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,492	06/01/2007	Takahide Kohro	032217A	1086

38834 7590 05/27/2009

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EXAMINER	
PAGONAKIS, ANNA	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,492	KOHRO ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 7-9 are currently under examination and the subject of this Office Action.

Applicant's amendment filed 4/3/2009 has been received and entered into the present application.

Claims 1-15 are currently pending. Accordingly, claim 7 is amended and claims 1-6 and 10-15 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b) as being directed to non-elected subject matter.

Applicant's arguments, filed 4/3/2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention.

Present claims are directed to a method of promoting transfer of Cdc42 protein from outside a nucleus of a cell into the nucleus of the cell by administering an isoprenoid synthesis inhibitor and/or geranylgeranyl transferase inhibitor and transferring Cdc42 protein from outside the nucleus of the cell into the nucleus of the cell. The specification and claims as originally filed fail to provide adequate written description for the newly amended active step of "transferring Cdc42 protein from outside the nucleus". Applicant has not provided Applicant any direction as to where the newly added claim

limitations can be found in the instant disclosure. Upon review of the disclosure, no such limitation "transferring Cdc42 protein from outside the nucleus" was found. While it is recognized that adequate written description of a limitation is not required to be stated in *haec verba* in the specification or claims as originally filed, adequate written support for all claim limitations must arise from either an explicit or implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention.

MPEP 2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement, does the description clearly allow persons of ordinary skill in the art to recognize that he or she invention what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter," *Ralston Purina Co. v. Far-Mar-Co., Inc.* 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))… Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Masamura et al (Arterio Thromb. Vasc. Biol, 2003, provided by Applicant).

Masamura et al. teach that HMG Co A reductase inhibitors are effective for improving arteriosclerosis and other vessel-related diseases, and one of the said statins, pitavastatin is particularly employed.

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if transfer of Cdc42 protein into the nucleus was not itself recognized as a pharmacological effect of administering the elected compound of Masamura et al. to a patient exhibiting artherosclerossis or other vessel-related diseases, Though new properties of a compound are not doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 102 is based upon the therapeutic applications and effects of the compounds, not the mechanisms or properties by which they exert such a therapeutic effect.

Please also see Ex Parte Novitski, 26 USPQ2d 1389 (Bd. Pat. App. And Inter. 1993), which stated, "The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of P. cepacia. A U.S. Patent to Dart disclosed inoculating using P.cepacia type Wisconsin 526 bacteria for protecting the plant from fungal

disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that Applicant had stated in the specification that Wisconsin 526 an 18 percent nematode inhibition rating." Analogously, in the present case, though Masamura et al does not explicitly note the function of the elected compound as a promoter of transfer of cdc42 protein into the nucleus, such a property, though only now recognized by Applicant, is an inherent property of the elected compound, absent factual evidence to the contrary.

Applicant's Remarks

Applicant alleges that the transfer of Cdc42 protein into the nucleus is not disclosed by Masamura et al and therefore does not disclose, teach suggest or provide any reasoning of the presently claimed method.

Response to Applicant's Arguments

Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Newly amended claim 7 (and the claims dependent therefrom) remain properly rejected because Applicant has amended claim 7 to now read upon transferring Cdc42 protein from outside the nucleus of the cell into the nucleus of the cell. This newly added limitation according to the claimed invention inherently results in the claims function(s) of transferring the Cdc42 protein by the cell from one location to another.

In view of the reasons stated in pages 8-9 of the Office Action mailed on 10/3/2008, whatever properties or characteristics of the claimed compound pitavastatin that Applicant has attributed to such a compound, i.e, that it functions to transfer Cdc42 protein from outside of the nucleus of the cell into the nucleus of the cell, are necessarily present in the method of using the same compound as disclosed by

Masamura et al., absent evidence to the contrary, because properties or effects of a compound are not severable from the compound itself. Please see MPEP 2112.

Preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims; case does not present situation in which new use of process should be considered limiting because it distinguishes process over prior art and voluntary amendment adding preamble language, made after examiner indicated that claims were allowable, does not create material limitation.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. In re Hirao 190 USPQ 15, 16-17, (CCPA 1976) held that the preamble was non-limiting because it merely recited the purpose of the process, which was fully set forth in the body of the claim.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Morikawa et al (Atherosclcor Thromb. Vasc. Biol, 2003, vol. 23: 512-517, provided by Applicant).

Morikawa et al. teach that HMG Co A reductase inhibitors are effective for improving arteriosclerosis and other vessel-related diseases, and one of the said statins, pitavastatin is particularly employed.

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if transfer of Cdc42 protein into the nucleus was not itself recognized as a pharmacological effect of administering the elected compound of Masamura et al. to a patient exhibiting artherosclerossis or other vessel-related diseases. Though new properties of a compound are not doubt important contributions to scientific and pharmaceutical development, the assessment of patentability

under 35 U.S.C. 102 is based upon the therapeutic applications and effects of the compounds, not the mechanisms or properties by which they exert such a therapeutic effect.

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Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Newly amended claim 7 (and the claims dependent therefrom) remain properly rejected because Applicant has amended claim 7 to now read upon transferring Cdc42 protein from outside the nucleus of

the cell into the nucleus of the cell. This newly added limitation according to the claimed invention results in the claims function(s) of transferring the Cdc42 protein.

In view of the reasons stated in pages 9-10 of the Office Action mailed on 10/3/2008, whatever properties or characteristics of the claimed compound pitavastatin that Applicant has attributed to such a compound, i.e, that it functions to transfer Cdc42 protein from outside of the nucleus of the cell into the nucleus of the cell, are necessarily present in the method of using the same compound as disclosed by Morikawa et al., absent evidence to the contrary, because properties or effects of a compound are not severable from the compound itself. Please see MPEP 2112.

Preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims; case does not present situation in which new use of process should be considered limiting because it distinguishes process over prior art and voluntary amendment adding preamble language, made after examiner indicated that claims were allowable, does not create material limitation.

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Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645